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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,429	02/13/2002	Rosa Martani	3-31105A	8742

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,429	MARTANI, ROSA	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Notice of Appeal filed 01/12/04, Request for Extension of Time, Preliminary Amendment, and Request for Continued Examination filed 03/22/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/22/04 has been entered.

Double Patenting

Non-statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,083,531 ('531), in view of US 4,311,490 ('490). Although the conflicting claims are not identical, they are not patentably distinct from each other because '531 claims a solid pharmaceutical dosage form comprising active substance, filler, binding agent, and usual auxiliaries. The solid dosage form is disintegrates in the mouth within 15 seconds (claim 1). Filler and binder are found in claims 2. The density of the dosage form is found in claims 3 and 4. The amounts of the ingredients are found in claims 7 and 8. Lubricant is found in claim 12. The '531 patent does not claim the claimed disintegrant, including polymethylmethacrylate (claim 13), however, '531 claimed binding agent and usual auxiliaries (claim 1). The '490 patent discloses binder such as polymethylmethacrylate (column 5, line 4). Therefore, those of ordinary skill would expect a similar quick dissolve solid dosage form having the claimed disintegration time from the use of the instant invention given the claims of the '531 and the '490 patents. There are no unusual and/or unexpected results, which would rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of the '531 and '490, which set out a similar quick dissolve dosage form using similar ingredients.

Response to Arguments

Applicant's arguments filed 03/22/04 have been fully considered but they are not persuasive. The examiner maintains the double patenting rejection.

Applicant argues that the composition claims of the present invention are significantly different from that of Humbert. The disintegration agents disclosed in claim 13, are distinctly and chemically distinct from the binding agents disclosed in Humbert. In response to the applicant's argument, applicant's attention is drawn to claims 1 and 2 of the '531 reference. The claims require a) active agent, b) filler, c) binding agent, and usual auxiliary to form a dosage form having density of 200-1000 mg/ml, and disintegrates within 15 seconds. Accordingly, binding agent and usual auxiliary can be selected similar to the claimed disintegrating agent in order to obtain the same density as well as the same disintegrating time. To be more significant, the '490 patent discloses binding agent such as polymethylmethacrylate, which is one of the disintegrants being claimed in claim 13. Thus, those of ordinary skill would expect a similar quick disintegrate formulation from the use of the instant invention given the claims of '531 and '490. There are no unusual and/or unexpected results which would rebut prima facie obviousness.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The "active substance" is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. Step (a)(2) does not require the present of active substance". See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant's specification at page 6, 2nd paragraph, and pages 9-10, disclose dosage form of the invention requires active substance. Nonetheless, step a(2) of claim 1 does not contain active agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the active substance in an auxiliary solvent" in line 12. There is insufficient antecedent basis for this limitation in the claim. Step a(1) is granulating active substance, and dispensing in *either* an auxiliary solvent *or* a solution/dispersion of "the active substance in an auxiliary solvent" [step b(2)]? Was it the active substance dispensed in an auxiliary solvent of step b(2)?

Claim 1 is rejected in the use of step a(2). It appears that step a(2) does not contain an active substance. It is confusing because while the claim requires that the dosage form comprising active substance as well as other pharmaceutical ingredients, the steps of the process exclude the use of the active substance. Does this mean that

the claimed process is used to prepare: 1) dosage form having active substance, and 2) alternatively, a different dosage form having *no active substance* but just other pharmaceutical ingredients? Further clarification is requested.

Claims 13-26 are rejected as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 13-26 depend in claim 12, which is a cancelled claim. Applicant is required to cancel the claims, or amend the claims to place them in proper dependent form, or rewrite the claims in independent form.

Response to Arguments

Applicant argues that The examiner has rejected claims 1-11 under 112, 2nd paragraph as being based on a disclosure which is not enabling. For clarification purpose, the enablement issue is under 112, 1st paragraph. In any event, steps a(1) and a(2) are recited in the claim in an alternative manner, and therefore, if step a(2) is selected, the powder/granular consisting no active substance. Applicant states in the remarks at page 8 that the preamble in claim 1 requires a skilled artisan to practice claim 1 when starting, for example, with "other pharmaceutical ingredients", she has to follow step a(2) with step b(2) not b(1) to add in the active substance. In response to applicant's argument, nowhere in the claim requires step a(2) has to follow by step b(2). The claim language and applicant's remarks are contradicting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679.

Humbert-Droz teaches process for preparing fast disintegrating oral dosage form discloses in pages 5-6. It appears that Humbert-Droz is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate as claimed in step (c). However, it is the position of the examiner that no criticality is seen in the particular step, since the prior art obtains the same result desire by the applicant, e.g., fast disintegrating oral dosage. Although, Humbert-Droz does not teach compacting the prepared powder or granulate, the extra step does not impart patentability over the applied prior art. Applicant's desire to produce rapidly dissolving dosage form, Humbert-Droz produces rapidly dissolving oral dosage form. Thus, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation modify Humbert-Droz with the expectation of similar result, because Humbert-Droz teaches a rapidly dissolving oral dosage form having the same density and the same disintegrating time. With regarding to the composition claims, it is the position of the examiner that one of ordinary skill in the art would have been motivated to modify Humbert-Droz's composition to obtain the claimed invention because Humbert-Droz

teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within 15 seconds (pages 2-5).

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679, in view of Erdos et al. US 5,108,757.

Humbert-Droz teaches fast disintegrating oral dosage form comprising active agent, filler, binding agent (disintegration agent), and talc as lubricant pages 3-4, and claims 1-13. The dosage form can be a tablet, which disintegrate in the mouth within 15 seconds, and have a density of 200-1000 mg/ml (pages 5-6). The dosage form is prepared without applying any freeze-drying, or any compression force (page 5).

Humbert-Droz does not teach the claimed disintegrant. However, Humbert-Droz teaches the use of other auxiliaries.

Erdos teaches a tablet dosage form comprising known auxiliary agents, including talc, magnesium stearate, and croscarmellose (column 5, lines 5-11). Thus, it would have been obvious for one of ordinary skill in the art to modify the auxiliary agents of Humbert-Droz using the croscarmellose as a disintegrant agent in view of the teaching of Erdos with the expectation of providing a quick dissolve tablet useful in pharmaceutical art.

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679, and Bovenkerk et al. US 4,311,490.

Humbert-Droz is relied upon for the reasons above. Humbert-Droz does not teach the claimed disintegrant. However, Humbert-Droz teaches the use of binder.

Bovenkerk teaches binder such as polymethylmethacrylate (column 5, lines 4-5). Thus, it would have been obvious for one of ordinary skill in the art to modify the tablet composition of Humbert-Droz using the polymethylmethacrylate as a binding agent in view of the teaching of Bovenkerk with the expectation of providing a quick dissolve tablet useful in pharmaceutical art.

Response to Arguments

Applicant argues that Humbert-Droz does not teach the claimed disintegration. Contrary to the applicant's argument, there're no unusual and/or unexpected results in the use of the disintegrating agent. It is noted that Humbert-Droz also obtained the same density being claimed as well as the claimed disintegrating time. Accordingly, the burden is shifted to applicant to provide a side-by-side comparison showing the unexpected results over the use of Humbert-Droz's other auxiliaries. It is also noted that the polyvinylpyrrolidone teaches by Humbert-Droz can also be used as a dispersing agent (see The Merck Index at page 996).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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